REMARKS

Claims 1-10, 12-13, 15-24, 26-29, 31-32, 34-37, and 50 are pending in this application. Claims 39-49 and 51-53 are cancelled in this paper in accordance with a restriction requirement, without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications. Claims 11, 14, 25, 30, 33, and 38 have been cancelled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Claims 1, 5-10, and 12-13 have been amended; support for these amended claims can be found throughout United States Patent Application Publication No. 2004/0171147 A1 (hereinafter "the present application") at, for example, paragraphs [0011]-[0013] and [0019]-[0022] and [0039] and [0043].

Claims 18, 20, and 22-23 have been amended; support for these amended claims can be found throughout the present application at, for example, paragraphs [0039] and [0043] and [0050].

Claim 26 has been amended; support for this amended claim can be found throughout the present application at, for example, paragraphs [0039] and [0043] and [0051].

Claim 28 has been amended; support for this amended claim can be found throughout the present application at, for example, paragraphs [0039] and [0043] and [0051].

Claim 31 has been amended; support for this amended claim can be found throughout the present application at, for example, paragraph [0018].

Claims 34 has been amended; support for this amended claim can be found throughout the present application at, for example, paragraph [0019] and [0039] and [0043].

Claim 50 has been amended; support for this amended claim can be found throughout the present application at, for example, paragraph [0019] and [0039] and [0042]-[0043].

No new matter has been added.

Restriction/Election

The Examiner has imposed a restriction/election requirement. Office Action at pages 2-3. In accordance with the provisional election made on or about 18 August 2005, Applicant has cancelled claims 39-49 and 51-53. Applicant does so without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

The Rejections Under 35 U.S.C. § 112, ¶2 Should Be Withdrawn

On pages 4-5 of the Office Action, pending claims 10-11, 18-25, 28-30, and 34-38 are rejected as allegedly indefinite. In particular, the Examiner points to the following: 1) an allegedly unclear list of antigenic determinants in claim 10; 2) allegedly vague and indefinite uses of "derived from" in claims 11 and 34; and 3) allegedly vague and indefinite uses of "minimum numbers" in claims 18 and 28. As noted above, Claim 11, 25, 30, and 38 have been cancelled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications. The remaining claims have been amended to clarify the list and uses. As such, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 112, ¶2 be withdrawn.

The Rejections Under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

On pages 5-9 of the Office Action, claims 1-13, 15-24, 26-29, 31-32, 34-37, and 50 are rejected as allegedly failing to comply with the enablement requirement. In particular, based on the analysis of factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("*Wands* factors"), it is alleged that the pending claims are not enabled. Applicants respectfully traverse this rejection.

Without acquiescing to the rejections of the Examiner, and solely in order to promote the progress of the present application, Applicant has cancelled claim 11. As noted above, claim 11 has been cancelled without prejudice to Applicant's right to pursue the subject matter recited by it in one or more divisional, continuation, or continuation-in-part applications.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a

reasonable basis to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)). Accordingly:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement* ... unless there is *a reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support
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> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to *explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning* which is inconsistent with the contested statement.

Id. (emphases added).

Applicants respectfully submit that the pending claims are enabled because the present application "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

With respect to independent claims 1, 18, 31, 34, and 50 (and all claims dependent therefrom), the present application teaches the manufacture of the claimed cytotherapeutic units and libraries. Specifically, for example, the present application references well-known techniques for extracting cells from tissues, organs, fetal cord blood, a placenta, a postpartum placenta, and postpartum placenta perfusate at paragraph [0043]. The present application also references, for example, known methods of identifying, assaying, counting, sorting, separating, and storing said cells at paragraphs [0019] and [0028] and [0032]-[0035] and [0042].

Turning to independent claims 26 and 28 (and all claims dependent therefrom), the present application teaches the manufacture and use of kits comprising cytotherapeutic units. Specifically, for example and as noted above, the present

application references well-known techniques for extracting cells from tissues, organs, fetal cord blood, a placenta, a postpartum placenta, and postpartum placenta perfusate at paragraph [0043]. The present application also references, for example, methods of identifying, assaying, counting, sorting, separating, and storing said cells at paragraphs [0019] and [0028] and [0032]-[0035] and [0042].

The Examiner cites Pluchino *et al.*, 48 Brain Research Reviews 211-19 (2005) ("Pluchino") for the proposition that "significant questions need to be addressed before widespread use [of stem cell treatment strategies] in humans." Office Action at pages 6-7. Applicant acknowledges that some experimentation might be necessary to determine the types and numbers of cells to administer to each individual patient suffering from a particular condition. Applicant asserts, however, that this supposed experimentation would not represent undue experimentation. The determination by a physician as to whether a particular combination is effective in treating a disease in a given patient is a type of determination that is always made by physicians in the context of every medical treatment. The determination is a routine one that every physician is prepared to make. Indeed, armed with the teachings of the non-limiting prophetic examples related to acute myelogenous leukemia, sickle cell anemia, and adrenal leukodysplasia at paragraphs [0060]-[0062] of the present application, a physician could determine and dictate the numbers and types of cells that a patient needs- after taking into account such factors as the patient's condition, weight, and/or severity of disease- and direct the manufacture/organization of the claimed units, libraries, and kits and the use of same.

The Examiner cites Gerlach *et al.*, 249 [Suppl. 3] J. Neurol. III/33-III/35 (2002) ("Gerlach") to support the allegations (a) that there exist "multiple problems related to stem cell treatment" including "uncontrolled proliferation" and (b) that "long-term preliminary studies in animals" are necessary prior to administration of stem cells to human patients. Office Action at pages 7-8. Applicant respectfully submits that "variations in therapeutic effect" and "side effects" are part and parcel of most medical treatments- and may be part and parcel of those medical treatments involving units and kits as novel as the units and kits of the pending claims. The present application teaches physicians how to minimize or overcome certain effects; specifically, the present application teaches at paragraph [0060] stem cell combinations tailored in light of factors such as "the patient's weight, severity of disease or even changes in recommended treatment." In any event, Applicant

respectfully reminds the Examiner that suspected "variations" and "side effects" are relevant not to allowance of patent claims by the United States Patent & Trademark Office, but to approval of New Drug Applications by the United States Food & Drug Administration.

In addition, the Examiner cites Wobus & Boheler, 85 Physiol. Rev. 635-78 (2005) ("Wobus") to support the contention that "there are currently no embryonic stem cell based therapies on going in humans," in part due to multiple alleged issues related to said therapies. Office Action at pages 8. Applicant respectfully asserts that the Examiner has taken certain alleged teachings of Wobus out of context. While Wobus appears to reference certain putative challenges with respect to stem cell therapies, Wobus also highlights many successes in certain areas of stem cell research- specifically, for example, the successes of certain embryonic stem cell therapies in animal models of cardiac disorders, Parkinson's disease, and diabetes.[1] Wobus at pages 663-65. As such, Wobus may actually support Applicant's contention that the claimed inventions are enabled by the teachings of the present application, rather than bolster the Examiner's suggestion that the field of stem cell use is poorly developed.

On pages 9-13 of the Office Action, claims 14, 25, 30, 33, and 38 are rejected as allegedly failing to comply with the enablement requirement. In particular, based on the analysis of factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) ("*Wands* factors"), it is alleged that the pending claims are not enabled. The Examiner cites Stanworth & Newland, 1(5) Clinical Medicine 378-82 (2001) ("Stanworth") to support the contention that stem cell treatments involving gene therapy are "hindered by multiple difficulties." Office Action at page 11. According to the Examiner, Stanworth illustrates certain difficulties related to "vector design, efficiency of gene transfection, and lack of control of regulation of gene expression." *Id.* Applicants respectfully traverse this rejection.

Without acquiescing to the rejections of the Examiner, and solely in order to promote the progress of the present application, Applicant has cancelled claims 14, 25, 30, 33, and 38. As noted above, claims 14, 25, 30, 33, and 38 have been cancelled

[1] Applicant does not admit, of course, that Wobus (or any reference cited by Wobus) anticipates or renders obvious the pending claims.

without prejudice to Applicant's right to pursue the subject matter recited by it in one or more divisional, continuation, or continuation-in-part applications.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the pending rejections under 35 U.S.C. § 112, ¶1.

The Rejections Under 35 U.S.C. § 102 Should Be Withdrawn

Claims 1-8, 14-21, 23, 25-33, and 50 are rejected under 35 U.S.C. § 102(e). Office Action at pages 13-16. Specifically, the Examiner asserts that the claims are anticipated by United States Patent No. 6,461,645 ("Boyse"). Applicant respectfully traverses.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

Without acquiescing to the rejections of the Examiner, and solely in order to promote the progress of the present application, Applicant has cancelled claims 14, 25, 30, and 33. As noted above, these claims have been cancelled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Applicant respectfully submits that Boyse fails to teach each and every limitation of amended independent claims 1, 18, 26, 28, 31, and 50. Specifically, with respect to amended independent claims 1, 18, 26, 28, and 50, the Examiner has not established that Boyse teaches any one of a cytotherapeutic unit, a kit, or library comprising cells *from a plurality of sources*. Boyse allegedly teaches only the collection of cells from fetal/neonatal blood, wherever that blood may happen to reside (cord, placenta, or postpartum placenta). Boyse pointedly fails to teach sources of cells other than blood- such as, for example, fetal tissue, a placenta, a postpartum placenta, or postpartum placenta perfusate- recited by certain pending claims.

Turning to amended independent claim 31, the Examiner has not established that Boyse teaches a cytotherapeutic unit comprising cells obtained from a placenta.

Claims 1-4, 10, 14-21, 23, 25-33, and 50 are rejected under 35 U.S.C. § 102(a). Office Action at pages 16-18. Specifically, the Examiner asserts that the claims are anticipated by United States Patent Application Publication No. 2002/0132343 ("Lum"). Applicant respectfully traverses.

Without acquiescing to the rejections of the Examiner, and solely in order to promote the progress of the present application, Applicant has cancelled claims 14, 25, 30, and 33. As noted above, these claims have been cancelled without prejudice to Applicant's right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Applicant respectfully submits that Lum fails to teach each and every limitation of amended independent claims 1, 18, 26, 28, 31, and 50. Specifically, with respect to amended independent claims 1, 18, 26, 28, and 50, the Examiner has not established that Lum teaches any one of a cytotherapeutic unit, a kit, or library comprising cells *from a plurality of sources*, much less most (if not all) of the sources recited by the pending claims.

Turning to amended independent claim 31, the Examiner has not established that Lum teaches a cytotherapeutic unit comprising cells obtained from a placenta.

Claims 1, 4-5, and 11-13 are rejected under 35 U.S.C. § 102(a). Office Action at pages 16-18. Specifically, the Examiner asserts that the claims are anticipated by United States Patent Application Publication No. 2002/0102239 ("Koopmans"). Applicant respectfully traverses.

Without acquiescing to the rejections of the Examiner, and solely in order to promote the progress of the present application, Applicant has cancelled claim 11. As noted above, this claims has been cancelled without prejudice to Applicant's right to pursue the subject matter recited by it in one or more divisional, continuation, or continuation-in-part applications.

Applicant respectfully submits that Koopmans fails to teach each and every limitation of amended independent claim 1. Specifically, with respect to amended independent claim 1, the Examiner has not established that Koopmans teaches a cytotherapeutic unit comprising cells *from a plurality of sources*, much less most (if not all) of the sources recited by the pending claims.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the pending rejections under 35 U.S.C. § 102.

In sum, Applicant respectfully requests that the Examiner consider the present remarks and reconsider and withdraw all pending rejections. Should there by any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

Respectfully submitted,

DATE: 07 November 2005

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